

## **REMARKS**

### **Information Disclosure Statement**

In the March 6, 2009 Office Action, the Office indicated that because there is no translation provided for the Cañizares-Villanueva and the EP 0410236 reference, neither has been considered. Applicants submit herewith a Supplemental Information Disclosure Statement including U.S. Patent No. 5,364,563, which is the U.S. Patent that corresponds to EP 0410236. Also, applicants included the English Abstract for the Cañivares-Villanueva reference.

### **Rejection of Claims and Traversal Thereof**

In the March 6, 2009 Office Action:

claims 60-64 were rejected under 35 U.S.C. §112, second paragraph;

claims 60-61 and 63-64 were rejected under 35 U.S.C. §103(a) as being unpatentable over JP 06-070698 (hereinafter Sugimoto) in view of Borrer et al. (U.S. Patent No. 6,036,992) in view of Gladue et al. (WO 99/06585); and

claim 62 was rejected under 35 U.S.C. §103(a) as being unpatentable over Sugimoto in view of Borrer et al. in view of Gladue et al. as applied above in view of Place et al. (US Patent No. 6,261,590).

These rejections are hereby traversed and reconsideration of the patentability of the pending claims is therefore requested in light of the following remarks.

### **Rejection under 35 U.S.C. §112, second paragraph**

In the March 6, 2009 Office Action, claims 60-64 were rejected under 35 U.S.C. §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Applicants traverse such rejection.

According to the Examiner, “an algal derived DHA-rich phospholipid” is unclear because it could be interpreted as the phospholipids are from the algae or a mix with a DHA extract from algae and a phospholipid source.

Applicants have amended claim 60 to recite:

A method of preparing a coldwater fish feed composition which provides for an increased level of carotenoids in fish consuming same, the method comprising (a) mixing a carotenoid and phospholipids, **wherein the phospholipids have at least 20% fatty acid residues with 4 or more double bonds and are found in PUFA-rich extracts of single cell algal organisms** and are liquid at the body temperature of the coldwater fish to form a mixture; and (b) thereafter combining the mixture with at least one other animal feed component, such that the carotenoid makes up at least 1%, by weight, of the composition and the phospholipid makes up at least 5%, by weight, of the composition. (emphasis added)

As described in the instant specification at paragraph [0055], the “phospholipids of the present formulation can . . . be found in the PUFA-rich extracts of single cell organisms” and as such, it is clear that the phospholipids are from the algae. Further the amended claim clearly defines the type of fatty acids residues which one skilled in the art easily recognizes as ARA and/or DHA. Accordingly, claim 60 is definite. Withdrawal of the rejection under §112, second paragraph, is respectfully requested.

#### **Rejections under 35 U.S.C. §103(a)**

In the March 6, 2009 Office Action, claims 60-61 and 63-64 were rejected under 35 U.S.C. §103(a) as being unpatentable over JP 06-070698 (hereinafter Sugimoto) in view of Borrer et al. (U.S. Patent No. 6,036,992) (hereinafter Borrer) in view of Gladue et al. (WO 99/06585) (hereinafter Gladue). Applicants traverse such rejection.

According to the Office, Sugimoto does not expressly teach the inclusion of a phospholipid with algae material. Further it should be noted that Sugimoto clearly does not teach that 20% of the fatty acid residues must have 4 or more double bonds.

The Office states that Borrer “teaches that the microbial single cell oils may be used, particularly for the ARA and DHA fatty acid components of phospholipids.” However, the Office has missed that the Borrer reference clearly states that the level of long chain fatty acids  $\omega$ -6 is from 0.2 to about 0.6 percent and more preferably about 0.4 percent of the total lipid blend; and the level of long chain fatty acids  $\omega$ -3 is from about 0.06 to about 0.3 percent and more preferably about 0.12 percent of the total lipid blend. Clearly, these levels are very low and the direction of this reference is to stay at the 0.4 percent for  $\omega$ -6 fatty acids and 0.12 percent  $\omega$ -3 fatty acids (see column 4, lines 33-36 of Borrer). Thus, where is there

any guidance to go in the direction of applicants' claimed invention? There is none, and thus this proposed combination does not teach or suggest the presently claimed invention.

Further, the Appeal Board in *Ex parte Whalen*, 80 USPQ2d 1078, BPAI 7/2008, recently ruled that if the cited reference teaches a lower value for a specific property, then the cited reference does not lead a person of ordinary skilled in the art to modify the compositions and increase the level of specific components. As stated by the Board, when the reference teaches that the low level of long chain fatty acid is a desired property, then there is no teaching or suggestion to increase amount of long chain fatty acids in the composition. When Borrer describes the amount of long chain fatty acids, the amounts are narrowed to the center of the range and keep at the low amount of 0.4 percent for  $\omega$ -6 fatty acids and 0.12 percent  $\omega$ -3 fatty acids. Thus, Borrer does not provide any suggestion to "optimized" the level of the DHA fatty acid components of phospholipids.

With regards to Gladue, the Office recited that Gladue teaches that aquaculture feed needs to be nutritionally balanced so that the fish larvae receive proper nutrition and DHA significantly contributes to larval growth and survival.

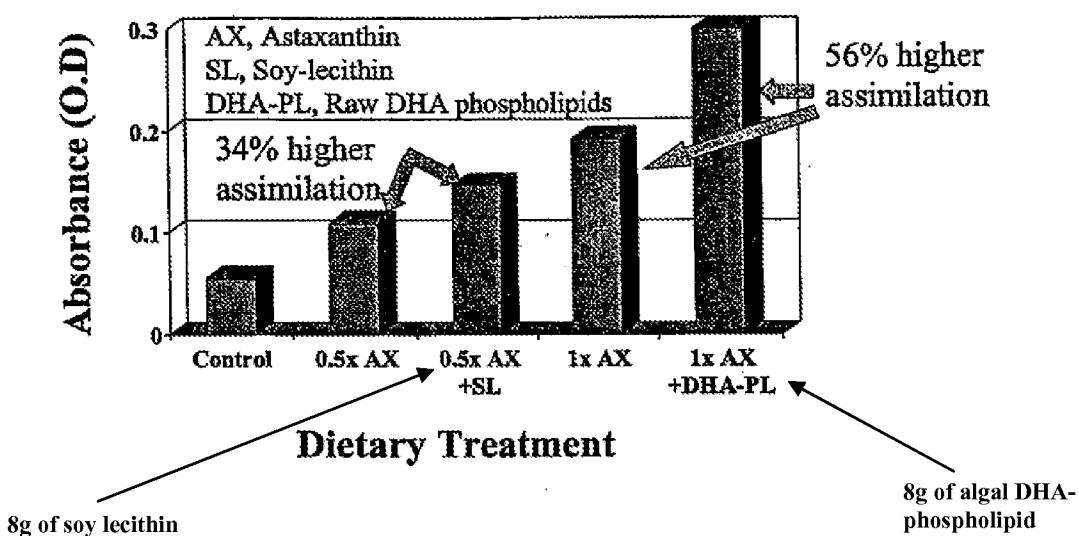
It is unclear how the Office came up with the combination of Sugimoto and Gladue. Sugimoto lists a number of different sources of phospholipid but, as noted by the Office, Sugimoto does not disclose the use of a phospholipid found in PUFA-rich extracts of single cells algal organisms. Gladue relates exclusively to the extraction of PUFA-rich phospholipids from algal organisms. Considered *in toto*, it appears as though the Office has resorted to hindsight reconstruction to combine Sugimoto and Gladue in an attempt to establish a *prima facie* case of obviousness, which is legally impermissible.

Applicants' claimed invention relates to a method of preparing a coldwater fish food composition that upon administration increases the takeup of carotenoids into the fish tissue. One skilled in the art considering Sugimoto and Gladue would not know that carotenoids such as astaxanthin are difficult to incorporate in coldwater fish and that combining the carotenoids with phospholipids found in PUFA-rich extracts of single cells algal organisms would significantly increase the uptake of the carotenoids in the muscle tissue of said coldwater fish.

Importantly, applicants have provided unexpected and superior results by using the feed of the present invention that includes phospholipids found in PUFA-rich extracts of single cells algal organisms in combination with carotenoids. For example, Sugimoto relates to the inclusion of a soy lecithin/astaxanthin mixture in the feed of Japanese amberjack, which is a warm water fish (see Example

1). When applicants incorporated a mixture of soy lecithin and *Phaffia* yeast (a natural source of astaxanthin) into the feed for trout (a coldwater fish), there was an increase in the uptake of the carotenoid in the muscle tissue (see Figure 1 reproduced hereinbelow wherein the increase was about 34%). However, unexpectedly, when applicants incorporated a mixture of phospholipids found in PUFA-rich extracts of single cells algal organisms with high content of DHA and *Phaffia* yeast in the feed for trout, there was a 56% higher assimilation of the carotenoid in the muscle tissue of the fish.

## Improved Total Carotenes (TC) Assimilation With DHA-PL (Trout)



It is important to note that the compositions used in the dietary treatments in the figure above contain exactly the same amount of a phospholipid but the one found in PUFA-rich extracts of single cells algal organisms is surprisingly more effective in aiding the absorption of the carotenoid. One skilled in the art considering both Sugimoto and Gladue would not reasonably expect that the use of phospholipids found in PUFA-rich extracts of single cells algal organisms with the carotenoids would significantly increase the uptake of carotenoids in the muscle tissue of coldwater fish.

It is well established that “if unexpected results are found then in fact the results are not obvious.” For example, the court in *In re Russell*, 169 USPQ, 412 (CCPA 1971) looked at the examples of the prior art to determine the line of guidance and teachings one skilled in the art would gain therefrom. Clearly the examples in Sugimoto teach that the use of soy lecithin is an acceptable phospholipid for the fish food

without any recognition that the administration of said fish food to a coldwater fish would result in inferior results relative to the fish food claimed by applicants herein. The *Russell* court concluded that “despite the fact that some of the claimed compositions are within the broad teachings of the prior art,” because applicants’ compositions showed unexpected advantageous properties, such compositions would not have been obvious. In light of this ruling, applicants insist that the presently claimed feed compositions made by the claimed invention are not obvious in light of Sugimoto and Gladue.

For the reasons discussed hereinabove, the Office has not met its burden of establishing a *prima facie* case of obviousness. Applicants therefore request that the rejection of claims 60-61 and 63-64 on the basis of obviousness be withdrawn.

2. In the March 6, 2009 Office Action, claim 62 was rejected under 35 U.S.C. §103(a) as being unpatentable over Sugimoto in view of Borror and Gladue as applied above in view of Place et al. (US Patent No. 6,261,590) (hereinafter Place). Again, applicants insist that the combination of Sugimoto, Borror, Gladue and Place does not defeat the patentability of the presently claimed invention. The shortcomings of Sugimoto, Borror and Gladue, as discussed above, are not overcome by the introduction of Place. Applicants submit that the Office has not established a *prima facie* case of obviousness and requests that all rejections under section 103 be withdrawn.

#### **Petition for Extension and Fees Payable**

Applicants request a one month extension and the \$65.00 fee is being paid electronically herewith. Applicants also added eight new dependent claims but also cancelled eight dependent claims thereby incurring no additional costs for the new claims. In the event, any additional fees are found due, the Commissioner is authorized to charge such fee to Deposit Account No. 13-4365 of Moore & Van Allen.

#### **Conclusion**

Applicants have satisfied the requirements for patentability. All pending claims are free of the art and fully comply with the requirements of 35 U.S.C. §112. It therefore is requested that Examiner Huang reconsider the patentability of the pending claims in light of the distinguishing remarks herein, and withdraw all rejections, thereby placing the application in condition for allowance. If any issues remain outstanding incident to the allowance of the application, Examiner Huang is requested to contact the undersigned attorney at (919) 286-8090.

Respectfully submitted,

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